DR. STEPHEN K. OPUNI

FDA/SMD/SM. 25/VOL1/13 April 18, 2013

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Dear Healthcare Professional,

AZITHROMYCIN AND CARDIOVASCULAR RISKS

The National Pharmacovigilance Centre at the Food and Drugs Authority has been informed by the innovator of Azithromycin (Zithromax and Zmax), Pfizer Global Pharmaceuticals that these products can cause abnormal changes in the electrical activity of the heart that may lead to a potentially fatal irregular heart rhythms or arrhythmias. The study by Pfizer showed that Azithromycin prolonged the QTc interval in dose- and concentration dependent manner. Pfizer Global Pharmaceuticals subsequently included the results of the study in azithromycin label to strengthen the Warning and Precautions section with information related to the risk of QT interval prolongation and torsades de pointes[1].

This followed a publication in the New England Journal of Medicine (NEJM) in May 2012 that compared the risk of cardiovascular death in patients treated with antibacterial drugs azithromycin, amoxicillin, ciprofloxacin and or no antibacterial drug[2]. The study revealed that there is an increase in cardiovascular deaths and in the risk of death from any cause, in persons treated with a 5-day course of azithromycin compared to persons treated with amoxicillin, ciprofloxacin, or no drug. The risk of cardiovascular death associated with levofloxacin treatment was similar to those associated with azithromycin treatment.

[1] http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/050710s039,050711s036,050784s023lbl.pdf
[2] http://www.nejm.org/doi/full/10.1056/NEJMoa1003833
[3] http://www.fda.gov/downloads/Drugs/DrugSafety/UCM343347.pdf

The United States Food and Drugs Administration (US FDA) has reviewed the available information and issued a Safety Announcement with respect to the safety of Azithromycin on March 12, 2013[3].

The Ghana Food and Drugs Authority will therefore like to caution healthcare professionals that Azithromycin can cause abnormal changes in the electrical activity of the heart that may lead to potentially fatal irregular heart rhythm. Patients at particular risk for developing this condition include those with known risk factors such as existing QT interval prolongation, uncorrected hypokalemia or hypomagnesemia, clinically significant bradycardia, and in patients receiving Class IA (quinidine, procainamide) or Class III (dofetilide, amiodarone, sotalol) antiarrhythmic agents.

Azithromycin is indicated for the treatment of the following conditions;

1. Acute bacterial exacerbations of chronic obstructive pulmonary disease
2. Acute bacterial sinusitis
3. Community-acquired pneumonia
4. Pharyngitis/tonsillitis
5. Uncomplicated skin and skin structure infections
6. Urethritis and cervicitis
7. Genital ulcer disease

In Ghana the Food and Drugs Authority has registered azithromycin with the following brand names; A-mycin, Azee, Azibest, Azifast, Aziglobe, Azimax, Azomax, Azithral, Aziron, Azithrin, Azivid, Azowok, Bexymicin, Maximycin, Shalzin, Inozith, Kibact, Zithromax and Zmax.

Meanwhile all healthcare professionals are encouraged to report any adverse drug reactions to azithromycin and any other medication to the National Pharmacovigilance Centre, Food and Drugs Authority by completing the blue adverse reaction reporting form or call **024 4310 297** or **drug.safety@fdaghana.gov.gh**. You may also download Adverse Drug Reaction Form from the FDA website, **www.fdaghana.gov.gh**.\

Further enquiries contact the FDA through the following address.

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Yours faithfully,

DR. STEPHEN K. OPUNI
CHIEF EXECUTIVE